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8EHQ-1001-14902

October 9, 2001

ROHM AND HAAS

Document Processing Center (TS-790)
Attention: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Contain NO CBI

Dear Madam or Sir:

We write to inform you that, on September 5, 2001, Rohm and Haas Company (R and H) completed its systematic review of certain categories of studies originally conducted or sponsored by Morton International Inc. (Morton), for compliance with the reporting requirements of Section 8(e) of the Toxic Substances Control Act (TSCA). R and H obtained these studies when it acquired Morton in June, 1999. R and H undertook this review in connection with its incorporation of the Morton studies into the R and H health and environmental effects database because the criteria that Morton used to evaluate its studies for reporting under Section 8(e) of TSCA, although similar, do not precisely match those used by R and H and toxicologists from the two companies may have differed in their evaluation of the reportability of specific studies. As described in our letters of March 27, and 30, 2001, R and H conducted this assessment and disclosed and mitigated potential violations in accordance with EPA's "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," 65 Fed. Reg. 19618 (April 4, 2000).

To minimize the potential for piecemeal identification, re-review and submission of legacy Morton studies under the R and H Section 8(e) reporting criteria, R and H conducted a systematic audit of those Morton studies most likely to include previously unreported 8(e) information. In particular, R and H reviewed environmental/ecotoxicity studies and repeat-dose mammalian studies conducted by or for Morton. At this time we have concluded our review. A list of the studies reviewed with the final reportability determinations is contained within the attached spreadsheet. A brief summary of our findings follows for your convenience.

The initial phase of the assessment included the review of a total of 133 ecotoxicity/environmental reports. This review was completed on March 14, 2001. On March 27, 2001, R and H submitted two aquatic toxicity studies to the 8(e) docket in accordance with Section 8(e) of TSCA. R and H notified the Toxics and Pesticides Enforcement Division of these potential violations in a letter dated March 30, 2001. Subsequently R and H submitted one aquatic toxicity study to the 8(e) docket on April 12, 2001. R and H also submitted 15 reports under FIFRA 6(a)2 on April 7, 2001 and notified the Enforcement Division of this submission in a letter dated April 18, 2001. R and H subsequently identified and reviewed 11 additional ecotoxicity studies. This supplemental ecotoxicity review was completed on August 16, 2001. On September 5,

2001, R and H submitted six avian toxicity studies to the 8(e) docket. These studies were conducted in 1978 and Morton's predecessor provided them to the 8(e) docket as "FYI" submissions at that time. These studies were therefore "previously known to the Administrator" and R and H does not believe that their redesignation as 8(e) submissions at this time constitute violations of TSCA. R and H notified the Enforcement Division of these submissions in a letter dated September 10, 2001.

R and H also reviewed 74 mammalian repeat-dose studies. These studies were reviewed in 4 phases. The first phase was commenced on May 1, 2001 and the final phase was completed on August 16, 2001. As a result of this review, R and H submitted a total of 16 mammalian toxicity studies under Section 8(e). Following the completion of the first phase of this review, R and H submitted 13 mammalian toxicity studies to the 8(e) docket on May 8-10, 2001. We informed the Enforcement Division of this submission in a letter dated May 16, 2001. As we indicated in our letter, ten of these studies were conducted prior to 1978 and were submitted to EPA within 15 days of their review. Thus, these submissions do not appear to constitute violations of TSCA section 8(e). Following completion of Phase 2 of this review, R and H submitted three additional mammalian toxicity studies to the 8(e) docket on June 21, 2001. The Enforcement Division was informed of this submission in a letter dated June 26, 2001. One of these studies was conducted prior to 1978 and was submitted within 15 days of its review. Therefore, its submission does not appear to violate TSCA.

We appreciate your attention to this matter and hope to resolve promptly any violations, without penalty, in accordance with EPA's Audit Policy. Please do not hesitate to contact Carolyne Hathaway at (202) 637-2279 or George Powell at (215) 592-2986 if you have any questions or require additional information.

Sincerely,

George J. Powell
TSCA Manager
EHS Corporate Center

cc: Ann Pontius, Acting Director
Toxics and Pesticides Enforcement Division

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	Yes 6a(2)	Date
A 28-Day Oral Toxicity Study in Rats Using C-3530 (Study No. 0436RM01.001)	99RM-1001	6/28/1999	X			
Advaflex LM-300 Co-Stabilizer: 28-Day Oral (Gavage Administration) Toxicity Study in the Rat with a 14-Day Treatment-Free Period (Report No. 1647/016-D6153)	98RM-1002	12/4/1998	X			
Advaflex LM-300 Co-stabilizer: Acute Oral Toxicity Study in the Rat (Fixed Dose Procedure) (Report No. 1637/11-D6144)	98RM-1017	6/10/1998	X			
K-37 (Copper-8-Quinolinolate): 80-Week Oral (Dietary) Carcinogenicity Study in the Mouse	94RM-1004	3/9/1994	X			
Copper 8-Quinolinolate: Technical CGA 281881: A Study of the Effect on Reproductive Function of Two Generations in the Rat (Lab Project ID 911382)	94RM-1010	3/11/1994	X			
Dibutyltin Dichloride: Oral (Gavage) Teratogenicity Study in the Rat (Project No. 380-211)	94RM-1012	11/11/1994	X			
Oral (Gavage) Embryotoxicity and Teratogenicity Study in the Rat with the Fungicide Ro 17-0099/000 (Copper 8-Quinolinolate). Segment II Study with Post Natal Evaluation	92RM-1002	1/13/1992	X			
Copper 8-Quinolinolate: 28 Day Repeated Dose Dermal Toxicity Study in Rats	92RM-1003	2/14/1992	X			
13 Week Oral Dietary Toxicity in the Rat with the Fungicide Ro 17-0099/000 (Oxine Copper)	91RM-1001	6/4/1991	X			

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	6a(2)	Date
K-37 (Copper 8-Quinolinolate): 13-Week Oral (Dietary) Rangefinding Study in the Mouse	90RM-1002	11/28/1990	X			
RO 17-0000/000: 13-Week Oral Toxicity Study (By Capsule) on Dogs (Lab Project ID B-154'807)	90RM-1013	10/15/1990	X			
RO 17-0099/000: 13-Week Toxicity Study (By Capsules) on Dogs (Maagdoc NR 041/9058) (Research Report No. B-144807)	90RM-1023	10/15/1990	X			
K37 Technical: 13-Week Oral (Dietary) Range-Finding Study in the Mouse (Toxicol Report Ref. No. TOM/1/90) (Maagdoc NR 041/9303)	90RM-1024 same as 90RM-1002	11/1/1990	X			
Benzyltriphenylphosphonium Chloride: Two-Week Inhalation Toxicity Study in Rats (DuPont LHR 36-89) current	89RM-1020	6/27/1989	X			
Tin and Organotin Compounds: Bibliography on the Neurotoxicology (Library Bibliography Number 12)	88RM-1012	1/1/1988	X			
K37 (copper 8-hydroxyquinolate): Rabbit Teratology Dose Ranging Study (Project ID AKJ/5/87)	87RM-1005 duplicate of 87RM-1010	4/1/1987	X			
K37 (Copper 8-Hydroyquinolate): Rabbit Teratology Study (Maagdoic NR 041/7384) (Project ID AKJ/6/87)	87RM-1009	8/1/1987	X			
K37 (Copper 8-Hydroxyquinolate): Rabbit Teratology Dose Ranging Study Maagdoic NR 041/7385) (Project ID AKJ/5/87)	87RM-1010	4/1/1987	X			
K37 (Copper 8-Hydroxyquinolate) Rabbit Teratology Dose Range Finding Study (Project ID: AKJ/5/87)	87RM-1011 duplicate of 87RM-1010	4/1/1987	X			
RO 17-0099/0000: 13-Week Toxicity Study in the Mouse (Maagdoc NR 041/3825) (Research Report No. B-104'777)	83RM-1011	2/5/1982	X			

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	6a(2)	Date
A 13-Week Toxicity Study with Ro 17-0099/000(Copper 8-Quinolinolate) in Mice p.o. (Feed Admix)	83RM-1013	2/28/1983	X			
Bis(Ortho-hydroxyphenyl disulfide): Range-Finding (14-Day) and Sub-Chronic (90-Day) Oral Toxicity Study (Report No. V82.128/202264)	82RM-1007	5/18/1982	X			
TM-582: Sub-Chronic (13-Week) Oral Toxicity in Rats (Report No. V81.006/2000651) (Project No. B80/0651)	81RM-1004	1/21/1981		X		5/9/2001
Hexaborcat: Short-Term (14-Day) and Sub-Chronic (90-Day) Toxicity Study in Rats (Report No. R-6612) (Project No. B79/2231)	80RM-1012	10/28/1980	X			
Vinyzene BP-5-Dermal and Systemic Toxicity Study Following Repetitive Dermal Application Over a 21 Day Period to the Intact and Abraded Skin of New Zealand Albino Rabbits (FDRL Lab. No. 5801)	79RM-1009	1/5/1979	X			
Teratology Study in Rats Using 10,10'-Oxybisphenoxarsine	78RM-1017	4/1/1978	X			
Cincinnati Milacron Sample 27K-125: The Subchronic Oral LD50 in Day-Old Leghorn Chickens (Lab No. 8E-2520)	78RM-1018	9/22/1978	X			
Cincinnati Milacron Sample 1185-111: The Subchronic Oral LD50 in Day-Old Leghorn Chickens (Lab No. 8E-2523)	78RM-1019	12/6/1978		X		9/5/2001
Cincinnati Milacron Sample 28H-047: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2522)	78RM-1020	12/6/1978		X		9/5/2001

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	6a(2)	Date
Cincinnati Milacron Sample 28G-082: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2521)	78RM-1021	10/10/1978		X		9/5/2001
Cancinnati Milacron Sample 1185-113: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2524)	78RM-1022	12/10/1978	X			
Cincinnati Milacron Sample 1185-114: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2525)	78RM-1023	12/10/1978		X		9/5/2001
Cincinnati Milacron Sample 1185-115: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2526)	78RM-1024	12/8/1978	X			
Cincinnati Milacron Sample 1185-117: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2527)	78RM-1025	12/9/1978		X		9/5/2001
Cincinnati Milacron Sample 1185-118: The Subchronic Oral LD50 in Day Old Leghorn Chickens (Lab No. 8E-2528)	78RM-1026	12/16/1978		X		9/5/2001
1175-99: Short-Term (13-Day) and Sub-Chronic (90-Day) Toxicity Study in Rats (Report No. R5716)	78RM-1028	8/29/1978	X			
Antimony Mercaptide 1165-14: Short Term (28-Day) and Sub-chronic (90-Day) Toxicity Study in Rats	78RM-1030	3/17/1978	X			
Short-Term (14-Day) and Sub-Chronic (90-Day) Toxicity Study with Antimony Mercaptide 1165-18 in Rats (Report No. R5627)	78RM-1031	1/3/1978	X			
Short-Term (14-Day) and Sub-Chronic (90-Day) Toxicity Study with LS201 in Rats (Report No. R5654)	78RM-1032	3/22/1978	X			

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	Yes 6a(2)	Date
Sub-Acute Oral Toxicity Study with Advastab 17 MOK in Chickens (Report No. R5850), (Project No. B78/1016)	78RM-1033	11/1/1978	X			
Sub-Acute Oral Toxicity Study with Advastab TM-692 in Chickens (Report No. R5915), (Project No. B78/1015)	78RM-1034	12/21/1978	X			
1175-99c: Subchronic (90-Day) Oral Toxicity Study in Rats (Report No. R 5831), (Project No. B77/1935)	78RM-1035	11/20/1978		X		5/8/2001
1175-114: Subchronic (90-Day) Oral Toxicity Study in Rats (Report No. R5873) (Project No. B77/1936)	78RM-1036	11/20/1978		X		5/8/2001
Teratology Study in Rats Using 10,10'-Oxybisphenoxarsine (LBI Project No. 20816)	78RM-1037	4/28/1978	X			
90-Day Subacute Oral Toxicity with Vinyzene SB-1 in Albino Rats (IBT No. 8560-08838)	76RM-1001	9/27/1976	X			
K-37 Technical: Two-Year Dietary Toxicity Study in Dogs (Project No. 854-103)	76RM-1013	2/18/1976	X			
Compound 1102-75: Sub-Chronic (90-Day) Toxicity Study (Rapport NrR-4940)	76RM-1023	10/29/1976	X			
Compound 1130-100: Sub-Chronic (90-Day) Toxicity Study in Rats (Rapport NrR-5226)	76RM-1024	12/1/1976	X			
Advastab TM-181 FS: 2-Generation Reproducion Study in Wistar Rats (Translation)	76RM-1026	1/11/1976	X			
Advastab TM-387:2-Generation Reproduction Dietary Study in Wistar Rats	76RM-1039	4/9/1976	X			

Study Title	Report No.	Study Date	Submitted to EPA			
			No	Yes 8(e)	6a(2)	Date
A Two Year Dietary Study in Dogs with K-37 (Project No. 854-103)	75RM-1010 interim report of 76RM-1013	1/14/1975	X			
A Two Generation Reproduction Study in Rats (Maagdoc NR 041/3217) (Project No. 854-105) with K-37	75RM-1011	5/30/1975	X			
Advastab TM-592: Sub-Chronic (90-Day) Toxicity Study in Rats (Rapport NrR-4674)	75RM-1014	5/1/1975	X			
Methyltin Stabilizer 1097-27: Sub-Chronic (90-Day) Toxicity Study in Rats (Rapport NrR-4737)	75RM-1015	7/22/1975		X		5/10/2001
Methyltin Stabilizer 1097-27, Methyltin Stabilizer 1087-103, Methyltin Stabilizer 1083-114; Sub-Acute (14-Day) Toxicity Study in Albino Rats (Rapport NrR-4630)	75RM-1016	3/7/1975		X		5/9/2001
Methyltin Stabilizer 1087-103: Sub-Chronic (90-Day) Toxicity Study in Albino Rats (Rapport NrR-4740)	75RM-1017	3/7/1975		X		5/9/2001
Trimethyltin Isocytylthioglycolate: Range-Finding (28-Day) Toxicity Study in Albino Rats (Rapport Nr R-4392)	74RM-1003	6/5/1974		X		5/8/2001
Trimethyltin Isoctylthioglycolate: Sub-Chronic (90-Day) Toxicity Study in Albino Rats (Rapport Nr R-4530)	74RM-1004	11/27/1974		X		5/8/2001
Advastab TM-185, Advastab TM-286, Advastab TM-387: 13-Week Dietary Administration to Rats Using Three Compounds (Project No. 452-109)	73RM-1007	8/8/1973		X		5/8/2001
Advastab TM-181 FS: Sub-Chronic (90-Day) Toxicity Study in Albino Rats (Rapport nr R-3995)	73RM-1008	2/1/1973	X			

Study Title	Report No.	Study Date	Submitted to EPA			
			No	Yes 8(e)	6a(2)	Date
Monomethyltin Tri-Isoctyl-Mercaptoacetate: Sub-Chronic (90-Day) Toxicity Study in Rats (Rapport Nr R-4062)	73RM-1010	4/25/1973		X		5/10/2001
Advastab TM-181 FS, Advastab T-270: 13-Week Dietary Administration to Rats (Project No. 452-106)	72RM-1002	1/7/1972		X		5/10/2001
Advastab TM-180, Advastab TM-181, Thermolite 831: 13-Week Dietary Administration to Rats	71RM-1004	11/15/1971		X		5/9/2001
Advastab TM-81 FS: Short-Term Feeding Study in Rats	71RM-1005	1/1/1971		X		5/9/2001
Results of 92-Day Dietary Feeding Studies on 10,10'-Oxybisphenoxarsine in Rats	69RM-1002	8/18/1969	X			
Bio-Guard Laundri-Stat T521F: Subacute and Chronic Dermal Application of Fabric Treated in Rabbits (Report No. R-238)	69RM-1003	12/19/1969	X			
Advastab A 70: Range-finding and Subchronic Toxicity Studies in Rats (Rapport Nr. R-2738)	68RM-1004	9/1/1968	X			
35 Day Dietary Feeding Study of 10,10'-Oxybisphenoxarsine to Rats	60RM-1001	9/13/1960	X			
Subacute 28-Day Oral Toxicity with Mortrace ST Conc. by Daily Gavage in the Rat (RCC Project 328162)	92RM-1027			X		6/21/2001
28 Day Subacute Dermal with Durotex 7487-A		8/31/1967	X			
Teratology Study in Rats with 10,10'-Oxybis-phenoxarsine (LBI Project No. 20816)		8/18/1977	X			
Subacute 28-Day Oral Toxicity With Mortrace SB Conc. by Daily Gavage in the Rat (RCC Project 327903)	92RM-1026	12/30/1992		X		6/21/2001

Study Title	Report No.	Study Date	Submitted to EPA			
			No	Yes 8(e)	6a(2)	Date
A Subchronic (3 Month) Oral Toxicity Study in the Rat with Formal [Bis (2-Chloroethoxy) Methane] (Project No. 89-3429)						
Carcinogenicity Study with Seven Materials in Swiss White Mice (IBT No. J8726)	92RM-1030	5/10/1972		X		6/21/2001
Advaflex LM-300 co-Stabilizer: 28 Day Oral (Gavage Administration) Toxicity Study in the Rat with a 14 Day Treatment-free Period (Report No. 1637/016-D6154	see 98RM-1002	12/1/1998	X			
2-Naphthalenol [(phenyl azo)phenyl] AzoHeptyl Derivative: Four-Week Toxicity and Reversibility Study Following Oral Administration to Rats (LSR Report No.: 90/MOH001/0226)		7/2/1990	X			
90-Day Subacute Oral Toxicity of Basic Calcium Periodate Albino Rats (IBT No. B4361)	66RM-1007	9/29/1966	X			
28-Day Subacute Dust Inhalation Toxicity Study with 4-Methylthiosemicarbazide in Albino Rats (IBT No. 663-04292)	75RM-1022	1/17/1995	X			
28-Day Subacute Dermal Toxicity Study with 4-Methylthiosemicarbazide (MTS) in Male Albino Rabbits (IBT No. 601-04289)	74RM-1027	2/12/1974	X			
90-Day Subacute Oral Toxicity Study with 4-Methylthiosemicarbazide in Albino Rats (IBT No. 622-04412)	74RM-1028	7/16/1974	X			
Repeated Dermal Toxicity in Rabbits Using Vinyzene BP-5	64RM-1002	11/21/1964	X			
Repeated Dermal Toxicity in Albino Rabbits Using Vinyzene BP-5	65RM-1003	2/15/1965	X			

Study Title	Report No.	Study Date	Submitted to EPA: No	Yes 8(e)	6a(2)	Date
Advastab TM-181 FS: Tin Accumulation Studies in Rats (Rapport Nr R-4192)	73RM-1009	9/11/1973	X			
Two-Year Dietary Administration in the Rat with K-37 (Project No. 854-104)	76RM-1012	3/26/1976	X			
RO 17-0099/000: Oral Pilot Study Pyramiding Doses in Male and Female Dogs (Maagdoc NR 041/8583) (Research No.B-154805) - K37?	90RM-1025	4/11/1990	X			